MAY - 4 2001

K003123
Page 1 of 2

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1. Submitter's Name: SUNDER BIOMEDICAL TECH. CO., LTD
   Address: 10F-1, 1-67, Wu-Chun Rd. Taichung, Taiwan
   Phone: 886-4-23755650
   Fax: 886-4-23755651
   Contact: Tony Hung

2. Device name: RENAX A.V. FISTULA NEEDLE SET
   SUNDER A.V. FISTULA NEEDLE SET
   Common Name: A.V. FISTULA NEEDLE SET
   Classification Name: NEEDLE, FISTULA

3. Classification: Class II Panel: 78 Product Code: FIE

4. Predicate Device: BIOTEQUE A.V. FISTULA NEEDLE SET

5. Device Description: SUNDER A.V.FISTULA NEEDLE SET consist of the following 6 major components: the stainless needle, protector cap for needle, the plastic butterfly wing, the PVC tubing, the female luer, the cap for female luer. These 6 major components assembled together as A.V. Fistula Needle Set for use during hemodialysis procedures. Various models of needle size manufactured such as 15 gauge, 16 gauge, 17 gauge.

6. Intended Use: **INDICATIONS FOR USE :**
   The RENAX A.V. FISTULA NEEDLE SET is used during hemodialysis. It is a part of accessory of extra corporeal system for treatment of renal failure. A. V. Fistula Needle applied on the access site of patient's vessel to obtain blood flow adequate to pass through the dialysis, and the reinfusion of dialysed blood back to patient via the fistula needle during hemodialysis.

USERS TO INSTALL THE DEVICE:
Trained nurses or the doctors.

ENVIRONMENT FOR THE DEVICE TO BE USED:
The hemodialysis center.

SPECIAL NOTES:
The Arterial-Venous Fistula (A.V.F.) Needle Set must be installed by trained nurses and doctors. The patients can not influence the use of the device.

7. Performance Summary: In terms of Physical specification, Chemical specification, Biological specification and Sterilization specification, the device conforms to applicable standards included ISO 10993 series, ISO 11607-1, ISO 11135, USP pyrogenic standards and related standards…etc.

8. Conclusions:
The SUNDER A.V. FISTULA NEEDLE SET has the same intended use and similar technological characteristics as the BIOTEQUE A.V. FISTULA NEEDLE SET (k993118). Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The SUNDER A.V. FISTULA NEEDLE SET is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Mr. Tony Hung
President
Sunder Biomedical Tech. Co., Ltd.
10F-1, 1-67, Wu-Chuan Rd.
TAICHUNG CITY
TAIWAN

Re: K003123
Renax® A.V. Fistula Needle Sets
Dated: February 1, 2001
Received: February 7, 2001
Regulatory Class: II
21 CFR §876.5540/Procode: 78 FIE

Dear Mr. Hung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) NUMBER (IF KNOWN) : K003123

DEVICE NAME : RENAX A.V. FISTULA NEEDLE SET

INDICATIONS FOR USE :

The RENAX A.V. FISTULA NEEDLE SET is used during hemodialysis. It is a part of accessory of extra corporeal system for treatment of renal failure. A. V. Fistula Needle applied on the access site of patient's vessel to obtain blood flow adequate to pass through the dialysis, and the reinfusion of dialysed blood back to patient via the fistula needle during hemodialysis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over –The-Counter-Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003123